

REMARKS

As an initial matter, Applicants' attorney notes, with appreciation, the in-person interview conducted by Examiner Tarla R. Patel and Primary Examiner Michael Phillips on June 17, 2009 with William Smith (Reg No. 46,459). Several issues regarding the pending final Office Action were discussed. First, the Examiner's objections to the drawings under 37 CFR 1.83(a) and the related rejection of independent Claim 12 as lacking antecedent basis under 35 U.S.C. § 112 were considered. It was concluded that the drawings filed with the application showed every feature recited in Claim 12, and that there was thus sufficient antecedent basis for that claim. The rejections of independent Claims 1 and 12 under 35 U.S.C. § 103(a) were also discussed with respect to the cited references: U.S. Pat. No. 6,599,235 to Kovac ("the Kovac Patent") and U.S. Pat. No. 6,981,983 to Rosenblatt, et al. ("the Rosenblatt Patent"). After a detailed discussion, it was concluded that neither Kovac nor Rosenblatt taught the use of an intravaginal splint to support the vaginal wall and prevent substantial movement and displacement of the reinforcing material while the re-fixed vaginal epithelium heals, as is recited in both Claims 1 and 12. The Examiner agreed to withdraw the finality of the pending Office Action upon submittal by Applicant's attorney of an amendment presenting the arguments made during the interview, and to issue a non-final Office Action based on an updated search. The Examiner prepared an Interview Summary, which was signed by the Primary Examiner and provided to Applicant's attorney at the interview. A copy of the Interview Summary is provided herewith.

By the foregoing amendments to the claims, Applicant's attorney acknowledges the Examiner's withdrawal of method Claim 45, which is discussed further below. The text of withdrawn Claim 33 is restored to the listing of claims, as required by the Examiner. The claim that was incorrectly numbered as Claim 42 has been deleted from the listing, as discussed

further below, and a new Claim 49 having the same wording as the deleted claim has been added.

Turning to the Office Action, the Examiner has withdrawn Claim 45 as being drawn to a non-elected species. By the foregoing claim amendments, the status identifier of Claim 45 has been changed to indicate that the claim has been withdrawn. However, Applicant's attorney notes that independent Claim 1 is generic to Claim 45. Therefore, Applicants' attorney respectfully requests that Claim 45 be rejoined to Claim 1 and examined on the merits, if Claim 1 is found to be allowable. For the sake of completeness, Applicant's attorney also notes that Claim 1 is generic to previously-withdrawn Claim 33, and that rejoinder and examination of Claim 33 was requested in the previous Amendment, which was filed on December 16, 2008.

The Examiner has objected to the drawings as failing to show (i) the positioning of a second reinforcing material over the exposed fascia of the posterior vaginal wall; and (ii) the re-fixing of the vaginal epithelium over the second reinforcing material and the fascia of the posterior vaginal wall, which are recited as steps of method Claim 12. Applicant's attorney respectfully submits that the features recited in these steps are shown in Figs. 7 and 8, which were filed with the application, and requests withdrawal of the aforesaid objection. The Examiner and her Primary Examiner indicated their agreement with this position during the interview of June 17, 2009.

The Examiner has objected to the presentation of withdrawn Claim 33 because the claim language was removed from the listing of claims. The missing claim language has been restored in the listing of claims presented in this Amendment After Final. Applicant's attorney respectfully requests withdrawal of the aforesaid objection.

The Examiner has objected to Claim 42, which was added by the Amendment filed on December 16, 2008, on the grounds that a Claim 42 was filed with the application and

subsequently cancelled. By the foregoing claim amendments, Applicant's attorney has removed Claim 42 from the listing of claims submitted with this Amendment After Final, indicated the status of Claim 42 as being cancelled, and added a new Claim 49 having the same wording as the removed claim. Applicant's attorney therefore respectfully requests withdrawal of the aforesaid objection.

Turning to the claim rejections, the Examiner has rejected independent Claim 12 under 35 U.S.C. § 112 as lacking antecedent basis for the recited steps of "(e) positioning a second reinforcing material over the exposed fascia of the posterior vaginal wall" and "(f) re-fixing the vaginal epithelium over the second reinforcing material and the fascia of the posterior vaginal wall". Applicant's attorney respectfully submits that sufficient antecedent basis for the recited steps is presented in Figs. 7 and 8 of the drawings and Page 10, line 22 through Page 11, line 6 of the specification, and respectfully requests withdrawal of the aforesaid rejection. The Examiner and her Primary Examiner indicated agreement with this position during the interview of June 17, 2009.

The Examiner has rejected Claims 1-15, 34 and 43-48 under 35 U.S.C. § 103(a) over the aforementioned Kovac Patent in view of the aforementioned Rosenblatt Patent. Claims 1 and 12 are the independent claims in the application. Applicant's attorney respectfully traverses this rejection for the following reasons, which were favorably considered by the Examiner and her Primary Examiner during the interview conducted on June 17, 2009.

Independent Claims 1 and 12 are directed to a surgical procedure for repairing a damaged vaginal wall. Claim 1 recites the following steps: (a) mobilizing the vaginal epithelium off of the underlying fascia of the damaged wall; (b) positioning a reinforcing material over the exposed fascia; (c) re-fixing the vaginal epithelium over the reinforcing material and the fascia; and (d) locating an intra-vaginal splint into the vagina such that the splint supports the vaginal wall and prevents substantial movement and displacement of the reinforcing material. In the

method of Claim 12, the surgical procedure of steps (a)-(c) of Claim 1 is performed on the anterior and posterior vaginal walls, followed by the location of the intra-vaginal splint as in step (d).

Turning first to the Kovac Patent, the surgical method disclosed therein is performed to correct urethral hypermobility, rather than to repair damage to the anterior or posterior walls of the vagina. In the disclosed method, a mesh is used to construct a urethral sling which is supported by self-tapping bone anchors (see, e.g., Figs. 10 and 11), rather than being placed over the exposed fascia of the vaginal wall. The Examiner suggests that the Rosenblatt Patent discloses an intra-vaginal splint and that it would be obvious to employ such a splint in combination the surgical method taught by the Kovac Patent. Even if the Rosenblatt Patent disclosed such a splint (which it does not), there would be no motivation to use the splint since the mesh is already supported by the bone anchors.

Turning now to the Rosenblatt Patent, the surgical methods disclosed therein do not employ the steps (a)-(c) discussed above with respect to Claims 1 and 12. Rather than methods that require the making of incisions, the Rosenblatt Patent teaches the use of fixation devices for fastening intact anatomic structures to each other (see, e.g., Abstract and Col 3, lines 41-62). The Examiner identifies Fig. 25D of the Rosenblatt Patent as a disclosure of an intra-vaginal splint, such as that recited in Claims 1 and 12 of the present application. However, the text running from Col. 19, line 45 through Col. 21, line 28 explains that Figs. 25A-25D illustrate a template for guiding placement of devices for affixing soft tissue to supporting structures and for diagnosing the anatomical irregularities responsible for pelvic floor defects. In the context of its use as a diagnostic instrument, the template is placed in the vagina before the surgical procedure to replicate forces that would be applied to the pelvic floor by the vaginal repair (see Col. 21, lines 13-28). Thus, the template is used either before the surgical repair as a diagnostic tool, or during the repair to guide positioning of the fixation devices. Further, there

is no suggestion in the Rosenblatt Patent that the template would remain in the vagina after the repair. In contrast, the intra-vaginal splint of the present application is located so as to support the vaginal wall and prevent movement and displacement of the reinforcing material while the re-fixed vaginal epithelium heals (Page 7, lines 28-32 and Page 14, lines 5-10 of the present application).

For the reasons given above, Applicant's attorney believes that independent Claims 1 and 12 are not anticipated by the disclosures of the Kovac Patent or the Rosenblatt Patent, either alone or in combination. Therefore, the rejection of these claims should be withdrawn. The Examiner and her Primary Examiner agreed with this position during the interview of June 17, 2009.

Applicant's attorney respectfully submits that independent Claims 1 and 12 are patentably distinguishable over the combination of the Kovac Patent and the Rosenblatt Patent, and, therefore, should be allowed. Further, Applicant's attorney respectfully submits that dependent Claims 2-11, 13-15, 34, 44, and 46-49 should be allowed because they depend from allowable independent claims. Therefore, Applicants respectfully request reconsideration and allowance of all of the aforementioned independent and dependent claims. Applicants also respectfully request that Claims 33 and 45 be examined and allowed because they depend directly or indirectly from Claim 1, which is allowable and generic to both Claims 33 and 42.

Applicant's attorney respectfully requests that the finality of the pending Office Action be withdrawn as agreed during the interview of June 17, 2009. Since this Amendment is, in accordance with the Examiner's instructions, submitted as an Amendment after Final, a Request for Continued Examination (RCE) is not required for the finality of the pending Office Action to be withdrawn. Therefore, a RCE is not submitted herewith. Applicant's attorney further requests that the Examiner **immediately** notify Applicant's attorney by

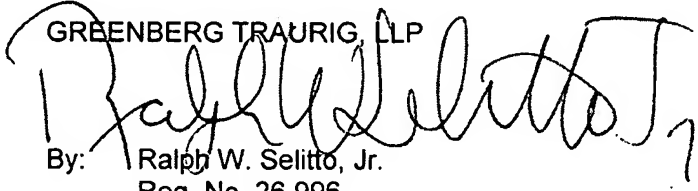
telephone at the telephone number provided below, if, for any reason, the finality of the pending Office Action cannot be withdrawn in the absence of an RCE.

This Amendment After Final is accompanied by a Petition to extend the time for response to the pending Office Action by one month to, and including, July 5, 2009. Authorization is provided in the Petition for the Examiner to debit Deposit Account No. 501561 in the amount of \$130 for the required petition fee. Applicant's attorney believes that no other fees are due with this Amendment After Final. If any such fees are due, including any petition fees or fees for extending the time for response, the Examiner is authorized to charge any deficiency to Deposit Account No. 501561.

If any issues remain that affect the patentability of the claims remaining in the application, or if issues arise from the submittal of this Amendment After Final that may prevent its entry in the application, the undersigned attorney invites the Examiner to contact him by telephone at the number listed below.

Respectfully submitted,

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